No. 04-32

IN THE

Supreme Court of the United States

MEDRAD, INC.,

Petitioner,

v.

LIEBEL-FLARSHEIM COMPANY
and MALLINCKRODT INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit properly applied well-settled principles of patent law governing claim construction to the patents in suit.

DISCLOSURE STATEMENT

Respondent Liebel-Flarsheim Co. is a wholly-owred subsidiary of Mallinckrodt Inc. Mallinckrodt Inc. is in turn a wholly-owned subsidiary of Tyco International, Ltd. a publicly traded company. No publicly-held company owns 10% or more of the stock of Tyco International, Ltd.

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R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. Pa. L. R. 1105 (2004) 11

The Petition presents no general legal issue meriting review much less any controversial questions of law demanding this Court's attention. There is no division within the Federal Circuit over the well-settled principle of patent law that it is the claims of a patent that define the invention to which the patentee is entitled the right to exclude and that, even where a patent describes a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit claim scope using words or expressions of manifest exclusion or restriction. This principle fully respects the claim-based system for defining inventions in effect since 1836 and inevitably calls for a patent-specific inquiry. The Federal Circuit's application of this principle in this case was a fact-specific application of time-honored principles of claim construction to the patents in suit and was correct. Petitioner's challenge to the decision presents only case-specific issues not appropriate for review by this Court and should be denied.

COUNTER-STATEMENT OF THE CASE

I. Procedural History

Respondent Liebel-Flarsheim Co.[1] brought the present action in 1998 alleging, among other things, that Petitioner Medrad, Inc. was infringing, inducing infringement of and contributorily infringing upon four L-F patents all directed to L-F's new and unique front-loading powered medical injector and syringes and controls therefor for delivering

1. Mallinckrodt Inc., the parent of Liebel-Flarsheim Co., was added as a party on the motion of Petitioner. Liebel-Flarsheim Co. and Mallinckrodt Inc. will be referred to collectively as "L-F".

contrast agents to patients during certain medical diagnostic procedures.[2]

The district court granted Petitioner summary judgment of non-infringement with respect to all four patents by orders filed October 18, 2001 and February 19, 2002. (Pet. App. 37, 105). The Federal Circuit reversed and remanded in a decision issued on February 11, 2004, holding simply and unremarkably that, absent a clear disclaimer of particular subject matter, the mere fact that the inventor disclosed only a single embodiment of his invention in the specification was not grounds to limit the claims of the patents to that particular structure. (App. 1, 8, 19-20). Petitioner's motion for rehearing and rehearing *en banc* was denied on April 2, 2004. On April 7, 2004, Petitioner moved to stay issuance of the mandate pending filing of a petition for writ of certiorari. The Federal Circuit denied Petitioner's motion on April 13, 2004. Petitioner did not move in this Court for a stay. On issuance of the mandate and remand to the district court, Petitioner again moved for a stay. Petitioner's motion was denied by the district court.

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2. U.S. Patent No. 5,456,669 ("the '669 patent") entitled "Method of Front Loading an Injector and Injecting Fluid Into Animals Therewith", U.S. Patent No. 5,650,261 ("the '261 patent") entitled "Disposable Front Loadable Syringe", U.S. Patent No. 5,662,612 ("the '612 patent"), and U.S. Patent No. 5,920,197 ("the '197 patent") both entitled "Controlling Plunger Drives For Fluid Injections In Animals".

II. Background

L-F's patented inventions relate to a remarkable development in the field of medical diagnostic imaging equipment, specifically to front-loadable powered injectors and automatic control of the plunger driver during the injection process, for use in imaging such as in angiographic, computed tomography, magnetic resonance and ultrasound imaging procedures. Prior to L-F's inventions, powered injectors required that the syringes be inserted in the injector by a breech-load method. As the district court observed, loading of the syringes by the breech-load method was cumbersome, time-consuming, and inefficient and presented a cleanliness problem and posed a safety hazard. (Pet. App. 38).

As a result of L-F's inventive efforts in the late 1980s, L-F introduced to the marketplace the first front-loadable powered injection system. This system eliminated the disadvantages inherent in the breech-loading power medical injectors then the industry standard and provided benefits in terms of use, speed, efficiency, sterility, and cleanliness theretofore unavailable in the art. *Id.* As the Federal Circuit correctly observed, L-F's patents are directed to front loading, rather than breech loading powered injectors. (Pet. App. 3). After Petitioner introduced its version of a front loading powered medical injector, this suit was brought.

From the outset, Petitioner attempted to limit the asserted claims of the '669 and '261 patents to the particular embodiment disclosed in the specifications, which used a pressure jacket around the syringes. In an attempt to avoid a finding of infringement, Petitioner at every turn attempted to convince the district court and the Federal Circuit (and

now this Court) that a front-load powered medical injector which did not employ a pressure jacket was somehow different in kind from L-F's invention. However, Petitioner's litigation-induced position was belied by the record developed in the district court that included extensive evidence that in the design process the L-F inventors considered front-loading injector designs with and without a pressure jacket, that Petitioner itself viewed a pressure jacket version and a version without a pressure jacket throughout its development simply as "design alternatives" and that Petitioner believed then and now that the concept of a front loading powered medical injector, regardless of whether it used a pressure jacket, was a patentable invention.[3]

In addition, Petitioner filed its own later patent application which issued as U.S. Patent No. 5,383,858 ("the '858 patent"). (Opp. App. 1). In that application, Petitioner described two design alternatives. One was a front loading powered injector without a pressure jacket and one was a front loading powered injector with a pressure jacket. Figs. 1-

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3. Indeed, when Petitioner first introduced its version of a front loadable injector, it touted the advantages of front loading in its sales literature without any reference to a prèssure jacket:

> **NEW! Front Load Capability**
>
> One step syringe engagement
>
> One step disposal of the syringe and tubing . . . together as a unit . . . no need to disconnect tubing . . .
>
> . . .it's just that easy . . . no mess to clean up.
>
> **A *Quarter Turn* for One-Hand Operation**

(Opp. App. 14-15).

8; col. 3, l. 64 - col. 7, l. 36 and Figs. 9-10; col. 7, l. 37 - col. 8, l.51, respectively. Petitioner stated that the pressure jacket could be eliminated simply by making the syringe stronger, e.g., by using a relatively strong plastic or by providing the syringe with annular reinforcing ribs. ('858 patent at col. 9, l. 24-27) (Opp. App. 11).

With respect to the '612 and '197 patents, Petitioner sought to limit the asserted claims to a control system that sensed only the presence of an extender on a prefilled syringe.

In spite of over 100 years of this Court's precedent and numerous Federal Circuit decisions, the district court read into the asserted claims of the '669 and '261 patents a requirement for a pressure jacket because that was what was illustrated in the specification as the preferred embodiment. Contrary to Petitioner's statement of the case (Pet. 6), the district court did not reject any dictionary definition of the word "opening." To the contrary, the district court held that term "opening" was clear and unambiguous (Pet. App. 51-52), and neither party asserted the contrary on appeal. Rather, the district court simply violated this Court's and the Federal Circuit's oft-stated proscription on reading into patent claims limitations from the specification.

The district court rejected Petitioner's attempt to limit the scope of the asserted claims of the '612 and '197 patents finding ample evidence in the prosecution that the claims extended to a variety of syringe-related properties. (Pet. App. 72-77). But the district court then read into the asserted claims the limitation that syringe-encoded information be used *directly* in the control of the injector, a term nowhere found in either the claims or the specification and a reading of the claims proposed by neither party.

III. The Federal Circuit's Claim Construction

A. The '669 and '261 Patents

The Federal Circuit began its analysis of the '669 and '261 patents by reiterating the well-established need to respect both of two cautions: one against reading limitations appearing only in the specification into the claims that carry a plain broader meaning; the other requiring that the claims be read in view of the specification. (Pet. App. 10-11). This is a patent-intensive and case-specific inquiry. The court then recited its extensive precedent rejecting "the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." (Pet. App. 13-14). The court reiterated its *Teleflex* ruling that even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using "words or expressions of manifest exclusion or restriction." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002). (Pet. App. 14).

The court then examined several of the cases relied upon by Petitioner, specifically *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001), and *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999), and carefully pointed out the distinctions between the patents and prosecution histories in those cases. (Pet. App. 14-16). The court then cited a number of its other decisions noting that "[i]n each of those cases, however, there were specific reasons dictating a narrow claim construction beyond the

mere fact that the specification disclosed only a single embodiment or a particular structure." (Pet. App. 16-18).

The court then examined the common specifications for any evidence of a clear disclaimer of subject matter and, finding none, concluded that: "This case is therefore governed by the principle that '[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context.'" (Pet. App. 18-20) (citing *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003); *Teleflex*, 299 F.3d at 1328).

The court next examined the prosecution histories of the '669 and '261 patents and found that they were "squarely contrary to [Petitioner's] contention that all the claims of those two patents require injectors that use pressure jackets." (Pet. App. 20). The Federal Circuit noted that during prosecution L-F had replaced claims that had included references to a pressure jacket with new claims that did not, providing, in the words of the Federal Circuit, "a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets." The court further noted that during the prosecution of the '261 patent, L-F had specifically stated to the Examiner who allowed the claims that there was not "necessarily a pressure jacket" in the claimed devices. (Pet. App. 20-21).

Finally, the court examined the claims of the '669 and '261 patents and observed the juxtaposition of independent claims lacking any reference to any pressure jackets with dependent claims that add a pressure jacket limitation.

The court held that this provides "strong support for Liebel's argument that the independent claims do not require the presence of a pressure jacket." (Pet. App. 22) (citing *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001); *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998)). *See also Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302-03 (Fed. Cir. 2003) (the presumption that an independent claim does not have the limitation that is introduced for the first time in a dependent claim "is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging the limitation in the dependent claim should be read into the independent claim").

In sum, the Federal Circuit concluded that the asserted claims of the '669 and '261 patents do not expressly require pressure jackets, that Petitioner had failed to point to a clear disavowal of claim scope in either the written description or the prosecution histories and that, in fact, the prosecution histories were squarely contrary to Petitioner's argument. The court thus concluded that the district court's claim construction requiring pressure jackets was erroneous. (Pet. App. 26).

Thus, contrary to what Petitioner seems to argue, the court did not begin and end its analysis by looking at the ordinary meaning of the word "opening" but rather carefully and methodically examined all of the claims, the patent specifications and the prosecution histories. The Federal Circuit asked Petitioner to point to words of manifest exclusion of claim scope in either the patent specifications or the prosecution histories, and Petitioner was unable to do so.

B. The '621 and '197 Patents

The district court's claim construction was easily reviewed. The court noted that there was nothing in the words "related to" or "using" that required a direct as opposed to an indirect relationship. Petitioner pointed to nothing in the patent specifications that would limit the claims to a direct relationship. Petitioner pointed only to the prosecution. The Federal Circuit carefully examined Petitioner's prosecution-based argument and determined that the applicants had not disclaimed an "indirect" relationship.

Accordingly, since the plain language of the claims and prosecution history did not support a claim construction limiting the relationship between the physical indicia and the syringe properties to a direct relationship, the Federal Circuit reversed the district court's claim construction.

REASONS FOR DENYING THE PETITION

I. The Federal Circuit Has Properly Articulated The Well-Settled Principle That Absent A Clear Disclaimer Of Particular Subject Matter, Particular Embodiments Appearing In The Specification Will Not Be Read Into The Claims For The Purpose Of Limiting Their Scope.

Petitioner attempts to manufacture an issue meriting review by this Court by arguing that the law on claim construction in the Federal Circuit is "chaotic."[4] Petitioner

4. Petitioner cites articles reciting high reversal rates on claim construction in the Federal Circuit. However, a number of others, both judges and commentators, have referred to these figures as misleading and unreliable. Judge Lourie of the Federal Circuit attributes the reversal rates to several factors, including the fact that the appellate court "digs into" all of its appeals, that Federal Circuit clerks have technical backgrounds that most district court judges lack, that the Federal Circuit is a "semi-specialized" court, so "it's not surprising that we arrive at a different result from the district court." Further, he noted that papers commenting on the reversal rates fail to take into consideration unpublished opinions by the court upholding trial court claim construction rulings. In his view, patent litigation is "getting simpler," thanks to this Court's *Markman* ruling that claim construction is a matter of law for the judge, not the jury, to decide. 66 PTCJ No. 1639 at 580 (Sept. 26. 2003).

The article cited by petitioner for its statistic of a 74% reversal rate (29 out of 39 cases from approximately September 2002 through June 2003) itself notes that the majority of district court errors in claim construction were due to a district court's narrow claim construction, i.e., "the district courts have overlooked the ordinary and accustomed meaning of claim terms." David J. F. Gross, et al., *You Must be Mistaken: Federal Circuit 'Corrections' of District Court Claim Constructions (2002-03)*, 766 PLI/Pat at 34 (2003). The authors conclude that rather

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than adopting a cynical approach of moving cases to the Federal Circuit early, "the district court should focus on the 'plain meaning' of the terms in some fashion." The authors' "Bottom-line": "Just as patent lawyers may reasonably disagree about the meaning of claim terms, so will judges of the district courts and Federal Circuit." *Id.* at 61-62.

Wagner and Petherbridge also cited by Petitioner concluded that "a new Federal Circuit is emerging — one that appears to be more rules-driven and more consistent than before." R. Polk Wagner and Lee Petherbridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. Pa. L. R. 1105, 1179 (2004).

Nor does Judge Newman's dissent in *Housey Pharmaceuticals, Inc. v. Astrazeneca UK, Ltd.*, 366 F.3d 1348 (Fed. Cir. 2004), support Petitioner's assertion of "chaos." That case involved four patents addressing methods of screening for protein inhibitors and activators. At issue were the words "inhibitor or activator of a protein." The *patentee* sought a narrow construction of the claims to save them from invalidity. The district court, however, held that the words meant "a substance that has a greater effect on the phenotype of cells that express the protein of interest at a higher level than on the phenotype of cells that express the protein of interest at a lower level or not at all." *Id.* at 1351. The Federal Circuit affirmed. In doing so, the court looked at the plain and ordinary meaning of the claim language and also the specification and the prosecution history to determine if the patentee had disclaimed or disavowed claim scope. Looking at the intrinsic evidence, the court concluded that the patent did not clearly disavow its broad plain meaning. *Id.* at 1351-1353. Judge Newman in dissent observed that "[t]he specification, on its face, can support either theory . . .", *id.* at 1359, so it is difficult to discern her complaint. The business of judging often requires making choices. Judge Newman would have reversed the district court (thus adding to the reversal statistics) and remanded for the district judge to hear conflicting expert testimony (i.e., extrinsic evidence). *Housey's* petition for rehearing *en banc* was denied on August 25, 2004.

It is well to note that Judge Newman just this June joined the panel in *Linear Tech. Corp. v. Impala Linear Corp.*, 371 F.3d 1364, 1376 (Fed. Cir. 2004), in which the plain meaning of the term "concurrently" was determined using a dictionary.

accuses the Federal Circuit of ignoring what it labels a "*Markman*-type" approach to claim construction as opposed to "ordinary meaning." Petitioner is clearly wrong because the Federal Circuit's decision in this case shows adherence to *Markman* (Pet. App. 10) and a careful analysis of the claims, patent specifications and prosecution histories (i.e., the so-called intrinsic evidence) of all four patents in suit. Petitioner is clearly wrong when it portrays this case as having been decided based on extrinsic dictionary definitions without reference to the claims, specifications and prosecution histories. Nowhere did the Federal Circuit refer to competing dictionary definitions (i.e., non-technical versus technical) in arriving at its decision. The court simply looked at the simple, clear and unambiguous words "opening", "related to" and "using" and saw no basis in the claims themselves, the specifications or prosecution histories to limit the claims in the case of the '669 and '261 patents to the preferred embodiment and in the case of the '612 and '197 patents to a "direct" relationship nowhere referred to in the intrinsic evidence. Petitioner should recall that in the Federal Circuit, it did not argue as a basis for its appeal that the district court's definition was wrong. Petitioner should also recall that when the Federal Circuit challenged it to point to a clear disavowal of claim scope in either the written description or the prosecution histories, it was unable to do so. (Pet. App. 26).

Petitioner can prevail in this case only if this Court adopts Petitioner's proposed claim construction that in all cases patent claims can have a scope no broader than the particular embodiments described in the patent specifications. Petitioner's proposed claim construction, however, flies in the face of this Court's well-settled and long-standing jurisprudence as well as that of the Federal Circuit.

It has been a bedrock principle of patent law for well over 100 years that the claims of a patent define the invention to which the patentee is entitled the right to exclude. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("[T]he claims made in the patent are the sole measure of the grant."); *Altoona Publix Theatres, Inc. v. Am. Tri-Ergon Corp.*, 294 U.S. 477, 487 (1935) ("Under the statute it is the claims of the patent which define the invention."); *Smith v. Snow*, 294 U.S. 1, 11 (1935) ("[T]he claims of the patent, not its specifications, measure the invention."); *Continental Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 419 (1908) ("In making his claim the inventor is at liberty to choose his own form of expression, and while the courts may construe the same in view of the specifications and the state of the art, they may not add to or detract from the claim." (citation omitted)); *White v. Dunbar*, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public . . . to construe it in a manner different from the plain import of its terms."); *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876) ("[The statutorily required] distinct and formal claim is, therefore, of primary importance, in the effort to ascertain precisely what it is that is patented to the appellant in this case."). Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to "particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention." 35 U.S.C. § 112.

As Justice Bradley famously stated:

> Some persons seem to suppose that a claim in a patent is like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim; but not for the purpose of changing it, and making it different from what it is. The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms. This has been so often expressed in the opinions of this court that it is unnecessary to pursue the subject further.

White, 119 U.S. at 51-52; *see also Continental Paper Bag*, 210 U.S. at 419; *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116 (1895) ("[W]e know of no principle of law which would authorize us to read into a claim an element which is not present. . . . The difficulty is that if we once begin to include elements not mentioned in the claim . . . , we should never know where to stop.").

This principle is likewise firmly established in the Federal Circuit.[5]

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5. *Innova/Pure Water, Inc. v. Safari WaterFiltration Systems, Inc.*, 2004 U.S. App. LEXIS 16549, *15 (Fed. Cir. August 11, 2004) ("[P]articular embodiments appearing in the written description will not

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be used to limit claim language that has broader effect."); *Unitherm Food Systems, Inc. v. Jennie-O-Foods, Inc.*, App. Nos. 03-1472, -1473, 2004 U.S. Dist. App. LEXIS 14274, *24-25 (Fed. Cir. July 12, 2004) ("We have often stated that while . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims."); *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("While claims must be construed in light of the specification, limitations from the specification are not to be read into the claims, for it is the claims that measure the invention", internal quotations and citations omitted); *Taskett v. Dentlinger*, 344 F.3d 1337, 1340 (Fed. Cir. 2003) ("Though it is true that we must read a claim in light of the specification, rarely will we limit the claim to the preferred embodiments described in that specification."); *Anchor Wall Systems v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003) (concluding that including element in claim "would be to impermissibly read a limitation into the claims from the written description."); *Sunrace Roots*, 336 F.3d at 1304 ("We believe the district court erred in relying on various statements in the written description to conclude that the term shift actuator should be limited to a device containing the cam structure of the preferred embodiment."); *Abbott Labs. v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003) ("This court interprets patent claims in light of the specification, but this axiom does not mean that everything expressed in the specification must be read into all the claims. Claims are not necessarily and not usually limited in scope simply to the preferred embodiment", internal quotations and citations omitted); *RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1265 (Fed. Cir. 2003) ("[C]ourts may not use the teaching of the specification to contradict the clear language of the claims. To require the filter media of claim 1 to be multi-layered would impermissibly read limitations from the specification into the claim."); *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 318 F.3d 1143, 1149 (Fed. Cir. 2003) (concluding that to limit the claims "here would be to impermissibly read a limitation into the claims from the written description."); *Texas Digital Sys. v. Telegenix, Inc.*, 308 F.3d 1193, 1204
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(Fed. Cir. 2002) ("Consulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims."); *Teleflex*, 299 F.3d at 1326 ("As we have often stated, the claims must be read in view of the specification, but limitations from the specification are not to be read into the claims", internal quotations and citations omitted); *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002) ("While a court may look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim, extraneous limitations cannot be read into the claims from the specification or prosecution history."); *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1382 (Fed. Cir. 2001) ("This court will not limit a patent to its preferred embodiments in the face of evidence of broader coverage by the claims."); *Wenger Mfg.*, 239 F.3d at 1237 ("Although claims must be read in light of the specification of which they are a part, it is improper to read limitations from the written description into a claim."); *Tate Access Floors v. Maxcess Technologies, Inc.*, 222 F.3d 958, 966 (Fed. Cir. 2000) ("Although claims must be read in light of the specification of which they are a part, it is improper to read limitations from the written description into a claim", internal quotations and citations omitted); *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1362 (Fed. Cir. 2000) ("Specifically, we have noted the danger of reading limitations into the claims from the preferred embodiments".); *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999) ("Consistent with the principle that the patented invention is defined by the claims, we have often held that limitations cannot be read into the claims from the specification or the prosecution history."); *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 973 (Fed. Cir. 1999) ("The general rule, of course, is that the claims of a patent are not limited to the preferred embodiment, unless by their own language."); *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989-90 (Fed. Cir. 1999) ("[C]laim terms cannot be narrowed by reference to the written description or prosecution history unless the
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language of the claims invites reference to those sources."); *Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1347 (Fed. Cir. 1998) (noting it is a "well-established principle that a court may not import limitations from the written description into the claims"); *Comark Communications*, 156 F.3d at 1186 ("[L]imitations from the specification are not to be read into the claims."); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 866 (Fed. Cir. 1997); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) ("AST engages in a *post hoc* attempt to redefine the claimed invention by impermissibly incorporating language appearing in the specification into the claims."); *Electro Med. Sys. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994) ("[C]laims are not to be interpreted by adding limitations appearing only in the specification."); *Intel Corp. v. U. S. Int'l Trade Comm'n*, 946 F.2d 821, 836 (Fed. Cir. 1991) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims."); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 865 (Fed. Cir. 1988) ("References to a preferred embodiment, such as those often present in a specification, are not claim limitations."); *Intervet America, Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989)

> [T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into the claims, and that interpreting what is *meant* by a word *in* a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper

Internal quotations omitted; *Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988) ("[T]he general principle is that limitations from the specification are not to be read into the claims."); *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed. Cir. 1988) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims."); *SRI Int'l v. Matsushita Electric Corp. of Am.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) (*en banc*) ("That a specification describes only one embodiment does not require that each claim be limited to that one embodiment.").

Petitioner's Questions Presented thus presents no issues suitable for review by this Court. The decision below was correct and resulted from proper application of well-established patent law principles. Petitioner's complaint is simply with the result of an inquiry that is inevitably context-specific. Petitioner complains that the Federal Circuit's decision construing claims as they were drafted results in the claims covering a device not mentioned in the patent specifications, not invented by the patent applicants, and unknown in the art at time the original application was filed. Petitioner is again wrong. First, it is uncontested that L-F was the first to invent a front-loading powered medical injector and that the claims asserted in this action are directed to that broad invention. Second, the record below fully supported the fact that the inventors had conceived of both design alternatives, i.e., with and without a pressure jacket. The patent statute, however, requires only that a patentee describe a single mode for carrying out the invention. 35 U.S.C. § 112. Third, whether or not the patentees conceived of a version without a pressure jacket is wholly irrelevant for it is axiomatic that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121-22 (Fed. Cir. 1985). As this Court stated in *Smith v. Snow*:

> We may take it that, as the statute requires, the specifications just detailed show a way of using the inventor's method and that he conceived that particular way described was the best one. But he is not confined to that mode of use since the claims of the patent, not its specifications, measure the invention.

294 U.S. at 11 (citations omitted).

II. The Decision In This Case Is Not In Conflict With The Federal Circuit's Decision in *Microsoft Corp. v. Multi-Systems, Inc.*

Claim construction, of necessity, is an intensely context-specific exercise. Different patents for different inventions have different claims, different specifications and different prosecution histories. Statements made and actions taken in one case are wholly likely to be missing in another.

In *Microsoft Corp. v. Multi-Systems, Inc.*, 357 F.3d 1340 (Fed. Cir. 2004), the Federal Circuit reviewed the claims and specifications of the three patents in suit and the patentee's statements during prosecution and reached the "inescapable conclusion" that the descriptions did not merely describe a preferred embodiment, "but more broadly described the overall inventions of all three patents." *Id.* at 1348. This determination was based in part on claim language of the '627 patent that "explicitly states that the transmission of data . . . between the local site and a remote site must occur 'over a telephone line.' " *Id.* at 1348, and the patentee's concession that all of the claims require the use of a standard telephone line (whether expressly recited in the claims or not), and statements made in the prosecution history of the '627 patent. *Id.* at 1349.

The Federal Circuit in *Microsoft* applied the same approach to claim construction as it did in this case. It thoroughly examined the claims, specifications and prosecution histories and determined that transmission of data "over a telephone line" was not just a preferred embodiment. *Microsoft* is thus not unlike other Federal Circuit cases cited and distinguished by the Federal Circuit in its decision

in this case. (Pet. App. 14-18). There is no conflict, simply different records.[6]

III. Petitioner's Argument That The Federal Circuit's Decision Erodes The Role Of The PTO And The Patent System Is Misplaced

Petitioner argues that part of the PTO's function is to reject any claims it finds are unsupported by the specification and, should a court construe claims broadly (i.e., as they were written and allowed by the PTO), that this function is somehow compromised. This argument lacks credibility in the abstract and in particular has no application in this case.

As the Federal Circuit pointed out in its analysis with respect to the '669 and '261 patents, the PTO Examiner had before him independent claims that did not recite a pressure jacket and dependent claims that included the recitation of a pressure jacket. Accordingly, the PTO Examiner clearly knew the scope of the claims he was issuing. In addition, as the Federal Circuit also pointed out, in the prosecution of the '261 patent, the applicants stated to the PTO Examiner that in the claimed devices there is not "necessarily a pressure jacket." (Pet. App. 20-21). The PTO Examiner never rejected any of these claims as being unsupported by the specification. The simple reason is that the claims clearly are supported under the patent statute.

Petitioner further argues that the decision below erodes the patent system itself by eroding its notice function. Again, this argument carries no weight. All of the claims of the four

6. It is difficult to understand how these two cases can represent an "intracircuit split" when two of the three judges were common to both panels and the decisions were issued within days of each other.

patents in suit were thoroughly examined by the PTO and issued without limitation to a pressure jacket or direct use of electrical signals in the injector control circuitry. Thus, the public was and is clearly on notice as to the scope of the claims. As issued by the PTO, they are not limited in the manner that Petitioner seeks to limit them.

Petitioner forgets that it is Petitioner who seeks to alter the plain scope of the claims issued by the PTO. Thus, there is no lack of notice to the public — only Petitioner's refusal to recognize the well-settled rules applicable in the PTO and in the courts that, under the patent statute, only a single embodiment need be described and that "an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord*, *supra.*

IV. Petitioner's Request That The Petition Be Either Granted Or Held Or Granted And The Judgment Vacated And Remanded Should Be Denied.

Lastly, Petitioner argues that the Federal Circuit's grant of an *en banc* rehearing in *Phillips v. AWH Corp.*, Federal Circuit Appeal Nos. 03-1269,-1286, should be grounds for either granting its petition, holding it or granting it, vacating the judgment and remanding pending the Federal Circuit's *en banc* opinion. *Phillips* is not grounds for granting any of Petitioner's requests.

First, this case did not involve competing technical or general purpose dictionaries or any other definitional sources. There was no dispute over the meaning of the words "opening", "related to," or "using." Petitioner's own '858 patent used the word "opening" as simply the portion of an injector housing for

receiving the rearward end of the syringe, with or without a pressure jacket.[7] All parties agreed that the asserted independent claims did not recite a pressure jacket limitation while certain dependent claims did. By applying the doctrine of claim differentiation, the Federal Circuit found strong support for the patentees' position that its independent claims were not limited as argued by Petitioner because it would have been redundant for the independent claims to have been limited to a scope of protection already provided by the dependent claims. Nothing similar is present in the *Phillips* appeal.

Nor did *Phillips* involve competing claim construction methodologies. Regardless of how the Federal Circuit answers the questions it poses regarding the appropriate use of dictionaries in claim construction, this Court's precedent cited above remains. Further, should *Phillips* be reversed and Judge Dyk's dissenting opinion be adopted, that result will not help Petitioner since Judge Dyk refused to read into the claims the limitations of the preferred embodiment as Petitioner seeks to do here.

Second, Petitioner had filed its own petition for rehearing *en banc*, which was pending shortly before the opinion in *Phillips* was issued. If there were some application of the questions posed by the *en banc* panel in *Phillips* to this case, Petitioner's petition for rehearing *en banc* would have been granted.

Third, the Federal Circuit itself is not withholding decisions on claim construction pending an *en banc* ruling in *Phillips*. Claim construction opinions are being issued by

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7. "[T]he injector housing 26 is provided with an essentially cylindrical opening 29 for receiving a rearward end of the syringe 22." (Opp. App. 8, col. 4, l. 19-21).

the Federal Circuit weekly with no mention that decisions regarding claim construction should be held up because of *Phillips*.[8] If the Federal Circuit is not holding claim construction decisions pending *Phillips*, there is no good reason for this Court to hold petitions for writ of certiorari from those decisions. Granting or holding petitions in this Court can only create a massive backlog of petitions. Granting petitions, vacating the judgments and remanding will only shift that backlog to the Federal Circuit.

Finally, the Federal Circuit's decision in this case only reversed a grant of summary judgment and remanded the case back to the district court. No trial date has been set, but it will be well into 2005. Petitioner will have ample opportunity to assess whatever applicability the Federal Circuit's *en banc* opinion in *Phillips* may have.

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8. *See, e.g., Glaxo Group Ltd. v. Apotex, Inc.*, 2004 U.S. App. Lexis 15489 (Fed. Cir. July 27, 2004); *Mars, Inc. v. H.J. Heinz Co.*, 2004 U.S. App. Lexis 15640 (Fed. Cir. July 29, 2004); *Elster Electricity LLC v. Schlumbergersema Inc.*, 2004 U.S. App. Lexis 15796 (Fed. Cir. July 30, 2004); *Neomagic Corp. v. Trident Microsystems, Inc.*, U.S. App. Lexis 16178 (Fed. Cir. August 5, 2004); *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 2004 U.S. App. Lexis 16549 (Fed. Cir. August 11, 2004); *Power Mosfet Technologies, LLC v. Siemens AG*, 2004 U.S. Lexis 17020 (Fed. Cir. August 17, 2004).

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be denied.

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